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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant: Frank F. Molock, et al

For : COLORANTS FOR USE IN TINTED CONTACT LENSES AND METHODS FOR THEIR PRODUCTION

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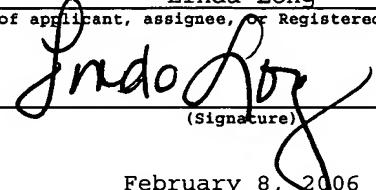
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February 8, 2006

(Date of Signature)

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Docket No. VTN 571

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Frank F. Molock

Serial No.: 10/027,579

Group Art Unit: 1779

Filed: December 20, 2001

Examiner: VARGOT, Matthieu

Title: COLORANTS FOR USE IN TINTED CONTACT LENSES AND METHODS FOR THEIR PRODUCTION

ATTENTION: BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANTS' BRIEF (37 C.F.R. 1.192)

This Appeal Brief is resubmitted in response to the Notification of Non-Compliant Appeal Brief, mailed on February 15, 2006. The original Brief was an appeal from the final rejection mailed November 17, 2004, a Notice of Appeal having been mailed on February 17, 2005.

The fees required under Section 1.17(f) were paid with the original Appeal Brief.

This brief is transmitted in triplicate. (37 CFR 1.192(a))

This brief contains these items under the following headings, and in the order set forth below (37 CFR 1.192(c)):

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1. **REAL PARTY INTEREST**

The real party in interest of the subject patent application is Johnson & Johnson Visioncare, Inc, having a principal place of business at 7500 Centurion Parkway, Suite 100, Jacksonville FL 32256.

2. **RELATED APPEALS AND INTERFERENCES**

There are no related appeals or interferences pending.

3. **STATUS OF CLAIMS**

Claims 24-26, 29, 30 and 41-43 are pending. Claims 1 through 23 and 31 through 40 have been withdrawn. Claims 27 and 28 have been canceled.

Claims 25-30 and 41 stand rejected under 35 U.S.C. 112.

Claims 24-30 and 41-43 stand rejected under 35 U.S.C. 103(a) in view of US 6,337,040 (Thakrar, et al.).

4. **STATUS OF AMENDMENTS**

The claims were amended on July 16, 2004 and February. Applicants believe that all amendments have been entered.

5. **SUMMARY OF CLAIMED SUBJECT MATTER**

The present invention as recited in the pending claims is related to a method for manufacturing a tinted contact lens comprising the steps of: a.) applying to a molding surface

of a mold a tinting-effective amount of a colorant comprising one or more pigments, one or more solvents and specifically recited binding polymers; b.) dispensing a lens-forming

amount of a lens material into the mold; c.) swelling the colorant in the lens material; and d.) curing the lens material in the mold to form the tinted contact lens, wherein the binding polymer and the lens material form an interpenetrating polymer network. Claim 24 recites binding polymers comprising copolymers of methacrylic acid and 2-hydroxyethyl methacrylate having a molecular weight of 7,000 to 100,000. Claim 42 recites a binding polymer comprising at least one hydrophobically-modified monomer selected from the group consisting of amides and esters of the formula:



Claim 43 recites a binding polymer comprising a homopolymer of 2-hydroxyethyl methacrylate having a molecular weight of about 7,000 to about 100,000.

6. GROUNDS OF REJECTION TO BE REVIEWED UPON APPEAL

Claims 25-30 and 41 have been rejected as indefinite under 35 U.S.C. 112 because "it is unclear whether dependent claims 25-28 are now properly limiting or definite based on the amendment" (November 17, 2004 rejection).

Claims 24-26, 29, 30 and 41-43 stand rejected under 35 U.S.C. 103 over us 6,337,040, (Thrakrar, et al).

7. ARGUMENTS

Claims 25-30 and 41 are definite under 35 U.S.C. 112

Claim 25

Examiner had rejected claims 25-30 and 41 and indefinite under 35 U.S.C. 112 in the November 17, 2004 final rejection. Applicants amended claim 25 in the February 17, 2005 amendment. However, upon further review in preparing this brief, it appears the rejection of claim 25 was not appropriate. Claim 25 as originally drafted recites that “the *lens material* comprises HEMA based hydrogels or silicone -based hydrogels”. [emphasis added]. Since no specific lens material is recited in claim 24, and claim 25 recites specific lens materials, claim 25 is definite as originally drafted. It is respectfully requested that the amendment of claim 25 not be entered. Claim 25 in the Appendix of Claims includes the amendments made on February 17, 2005.

Claim 26-28

Claim 26 was also amended and claims 27 and 28 canceled in the February 17, 2005 amendment. The advisory action mailed on March 16, 2005 states that the reply was entered, but does not state whether the amendments were entered or whether the rejections based upon 35 U.S.C. 112 have been withdrawn. Applicants respectfully request confirmation that the amendment to claim 26 have been entered and claims 27 and 28 have been canceled.

Claims 29, 30 and 41

No basis for rejecting claims 29, 30 and 41 under 35 U.S.C. 112 were given in the November 17, 2005 rejection, and claims 29, 30 and 41 do not appear to be indefinite. Applicants respectfully request confirmation that the rejection of these claims under 35 U.S.C. 112 has been withdrawn.

Claims 24-26, 29, 30 and 41-43 are patentable under 35 U.S.C. 103 over Thakrar, et al.

The present invention relates to a process for producing a colored contact lens using a binding polymer comprising one of three specifically defined polymers:

- copolymers of methacrylic acid and 2-hydroxyethyl methacrylate having a molecular weight of 7,000 to 100,000 (claim 24);
- polymer comprising at least one hydrophobically-modified monomer selected from the group consisting of amides and esters of the formula:
 - $\text{CH}_3(\text{CH}_2)_x\text{-L-COCHR=CH}_2$ (claim 42)
- a homopolymer of 2-hydroxyethyl methacrylate having a molecular weight of about 7,000 to about 100,000 (claim 43).

Claim 42

Thakrar et al. discloses producing a soft hydrogel colored contact lens via dispersing a coloring material in a carrier system which is compatible with the monomer material used to form the lens. Polymers comprising the amides and esters recited in the present claim 42 are neither disclosed nor suggested in Thakrar. Claim 42, is accordingly patentable over Thakrar et al.

Claims 24 and 43

Claims 24 and 43 respectively recite a 2-hydroxyethyl methacrylate copolymer and homopolymer having a molecular weight of 7,000 to 100,000.

Thakrar et al. is absolutely silent as to what molecular weight should be used to make a binding polymer containing 2-hydroxyethyl methacrylate, as recited in claims 24 and 43. The only disclosure or suggestion of the importance of molecular weight of the binding polymer came from the Applicants specification.

The Examiner rejected claims 24-36 and 41-43 as obvious in view of Thakrar (US 6,337,040) stating "one of ordinary skill in the art would have been able to pick and choose suitable resins and molecular weights from the resins generally taught in Thakrar et al". Page 3, November 17, 2004 rejection. Applicants respectfully disagree. Given the teaching of Thakrar, one of skill in the art would not have been directed to select any particular molecular weight. When polyHEMA which was commercially available at the time (300,000 MW from Aldrich, copy of page from Aldrich 2000-2001 catalog attached to Declaration of Dr. Douglas Vanderlaan, July 16, 2004) was used, the polyHEMA could not be dissolved in any of the solvents used in the Thakrar examples (1-butanol, 1-methoxy-2-propylacetate/cyclohexanone, cyclohexanone/methyl ethyl ketone, butoxy ethyl acetate). Based upon Thakrar et al. one of skill in the art might try other solvents (see column 3, lines 57-62), but there is no suggestion in Thakrar et al. to use poly(HEMA) of the molecular weight recited in the claims. The only suggestion to try molecular weights in the claimed range comes from the present application.

Claims 29 and 30

Applicants also note that claims 29 and 30 require two medium boiling solvents and one low boiling solvent. The low boiling solvent decreases the viscosity of the binding polymer solution. Mixtures of solvents, let alone the two medium/one low boiling point solvent mixtures are neither disclosed nor suggested by Thakrar. Accordingly, Applicants submit that claims 29 and 30 are patentable over Thakrar.

Reversal of the rejections is respectfully requested.

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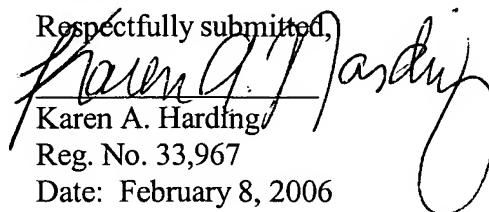
CONCLUSION

For the foregoing reasons, the reversal of the rejections relating to claims 24-26, 29, 30 and 41-43 are respectfully requested.

8. APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

(See attached)

Respectfully submitted,


Karen A. Harding

Reg. No. 33,967

Date: February 8, 2006

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8. **APPENDIX OF CLAIMS INVOLVED IN THE APPEAL**

24. A method for manufacturing a tinted contact lens comprising the steps of: a.) applying to a molding surface of a mold a tinting-effective amount of a colorant comprising one or more pigments, one or more solvents and a binding polymer having a molecular weight of about 7,000 to about 100,000 and comprising a copolymer of methacrylic acid and 2-hydroxyethyl methacrylate.; b.) dispensing a lens-forming amount of a lens material into the mold; c.) swelling the colorant in the lens material; and d.) curing the lens material in the mold to form the tinted contact lens, wherein the binding polymer and the lens material form an interpenetrating polymer network.
25. The method of claim 24, wherein the binding polymer has a molecular weight of about 7,000 to about 40,000 and the lens material optionally further comprises polymer units derived from silicone monomers.
26. The method of claim 24, wherein the binding polymer further comprises polymer units derived from lauryl methacrylate.
29. The method of claim 24 or 25, wherein the one or more solvents comprises two medium boiling point solvents and one low boiling point solvent.

30. The method of claim 29, wherein the two medium boiling point solvents comprise 1-ethoxy-2-propanol and isopropyl lactate.
41. The method of claim 24 wherein said pigment is coated or wetted with said binding polymer.
42. A method for manufacturing a tinted contact lens comprising the steps of: a.) applying to a molding surface of a mold a tinting-effective amount of a colorant comprising one or more pigments, one or more solvents and a binding polymer comprising at least one hydrophobically-modified monomer selected from the group consisting of amides and esters of the formula:



wherein L is selected from -NH or oxygen, x is a whole number from 2 to 24, R is selected from the group consisting of C₁ to C₆ alkyl or hydrogen; b.) dispensing a lens-forming amount of a lens material into the mold; c.) swelling the colorant in the lens material; and d.) curing the lens material in the mold to form the tinted contact lens, wherein the binding polymer and the lens material form an interpenetrating polymer network.

43. A method for manufacturing a tinted contact lens comprising the steps of: a.) applying to a molding surface of a mold a tinting-effective amount of a colorant comprising one or more pigments, one or more solvents and a binding polymer having a molecular weight of about 7,000 to about 100,000 and comprising a homopolymer of 2-hydroxyethyl methacrylate.; b.) dispensing a lens-forming amount of a lens material into the mold; c.) swelling the colorant in the lens material; and d.) curing the lens material in the mold to form the tinted contact lens, wherein the binding polymer and the lens material form an interpenetrating polymer network.

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9. **EVIDENCE APPENDIX**

The attached declaration was submitted by the Applicant on July 16, 2004, and was entered by the Examiner on November 17, 2004.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Frank Molock, et al.
Serial No. : 10/027,579
Filed : December 20, 2001
Title: COLORANTS FOR USE IN TINTED CONTACT LENSES AND
METHODS FOR THEIR PRODUCTION
Art Unit : 1732
Examiner : Mathieu Vargot

Honorable Commissioner of Patents
Alexandria, VA 22313

DECLARATION UNDER 37 CFR 1.132

I, Douglas Vanderlaan, PhD, declare as follows:

1.1 I am currently a Senior Scientist for Johnson & Johnson Vision Care, Inc. I received a Bachelor of Science in Chemistry from Calvin College, in 1979, and a Doctorate in Organic Chemistry from the Florida State University in 1984. I was a Research Fellow in the field of Organic Chemistry at the University of Michigan from 1984-1985. I was a Research Chemist at SWS Silicones from 1985-1986 and Senior Chemist at Reichhold Chemicals from 1986-1989. I have been a scientist for Johnson & Johnson Vision Care, Inc since 1989. In my tenure with Johnson & Johnson Vision Care, Inc. I have been engaged in research and study of materials for contact lenses

1.2 I reviewed the Examples of US 6,337,040 ("US '040") and tried to dissolve poly(2-hydroxyethylmethacrylate) (polyHEMA) in the solvents used in the Examples of US '040. No molecular weight was specified in US '040 for the binding polymers. The only molecular weight listed for polyHEMA in the 2000-2001 Aldrich Catalog was 300,000. A copy of page 1375 from the 2000-2001 Aldrich Catalog showing the polyHEMA entry is attached hereto.

1.3 I combined 2.0 g of poly(2-hydroxyethylmethacrylate) (300,000 M_v, from Aldrich Chemicals) with 8.0 g 1-butanol and mixed for 3 hours at room temperature. The polymer showed no signs of dissolving and did not appear to be swelling.

1.4 I combined 3.0 g of poly(2-hydroxyethylmethacrylate) (300,000 M_v, from Aldrich Chemicals) with 3.5 g 1-methoxy-2-propylacetate and 3.5 g cyclohexanone and mixed for 3 hours at room temperature. The polymer showed no signs of dissolving and did not appear to be swelling.

1.5 I combined 3.5 g of poly(2-hydroxyethylmethacrylate) (300,000 M_v, from Aldrich Chemicals) with 3.25 g cyclohexanone and 3.25 g methyl ethyl ketone and mixed for 3 hours at room temperature. The polymer showed no signs of dissolving and did not appear to be swelling.

1.6 I combined 1.5 g of poly(2-hydroxyethylmethacrylate) (300,000 M_v, from Aldrich Chemicals) with 8.5 g butoxy ethyl acetate and mixed for 3 hours at room temperature. The polymer showed no signs of dissolving and did not appear to be swelling.

1.7 None of the solvents used in the Examples of US '040 dissolved poly(HEMA) having a 300,000. Clearly US '040 did not appreciate the importance of molecular weight for binding polymers comprising poly(HEMA).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereof.

Inventor's Full Name

Douglas Vanderlaan, PhD

Douglas Vanderlaan
Signature

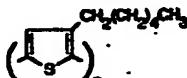
July 16, 2004

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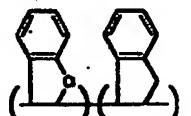
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■ Polyhexylite

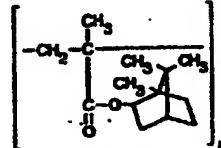
alcohol, bp 119° nD 1.3160	5mL	5	16.99	44,570-3	Poly(3-hexylthiophene-2,5-diyl), regioregular [104934-50-1] mp 238° For the characterization and solid-state properties of this polymer, see <i>J. Am. Chem. Soc.</i> 1994, 117, 233. Solid. Greater than 99.5% head-to-tail regiospecific conformation. Average M _w ca. 87,000	1g	229.35
$\text{H}_2\text{C}_2\text{OPO}_3\text{H}_2$	5mL	5	16.99		Product of Rieke® Metals, Inc.		
	25mL	5	43.00	51,082-3	Poly(3-hexylthiophene-2,5-diyl), regiorandom [104934-50-1] For solid state properties see <i>J. Am. Chem. Soc.</i> 1994, 117, 233 Red solid. Conducting polymer. 1:1 (head-to-head):(head-to-tail) linkages of regiosomers	1g	229.35
monoalkylamide 1.700	5g	5	15.99		Product of Rieke® Metals, Inc.		
	25g	5	43.00	49,709-6	Poly(4-hydroxybenzoic acid-co-ethylene terephthalate) [125300-07-4] [OC ₆ H ₄ CO ₂]-[OCH ₂ CH ₂ O ₂ CO ₂ H-4-CO ₂] _n Liquid crystalline copolyester	100g	20.00
monocarboxylic d 1.770 Fp none	5mL	5	16.99	43,234-2	Poly(4-hydroxybenzoic acid-co-6-hydroxy-2-naphthoic acid) [70579-32-4] [OC ₆ H ₄ CO ₂]-[OC-10H ₆ CO ₂] _n mp 280° d 1.500 Liquid crystal random thermoplastic copolymer. Average M _w >20,000. Reinforced with ca. 15% glass fiber	100g	21.10
	25mL	5	43.00	36,350-2	Poly(3-hydroxybutyric acid), natural origin [26063-00-3] [-COCH ₂ CH(CH ₃)O-] _n RAS 1(2),3163D T _g 172°C (DSC). Biodegradable polymer	10g	41.10
$\text{t}_2\text{CO}_2\text{H}$	250g	5	19.30	40,310-6	Poly(3-hydroxybutyric acid-co-3-hydroxyvaleric acid), natural origin [80181-31-3] [-COCH ₂ CH(CH ₃)O-] _n [-COCH ₂ CH(C ₂ H ₅)O-] _n , IgB +4.5% (c=0.1, CHCl ₃) RAS 1(2),3163E PHV content 5 wt. %	100g	265.40
D. Tm 55-65°	1kg	5	53.70		Produced via a controlled fermentation process using microorganisms. Biodegradable polymer		
	100mL	5	17.00	40,311-3	Poly(3-hydroxybutyric acid-co-3-hydroxyvaleric acid), natural origin [80181-31-3] [-COCH ₂ CH(CH ₃)O-] _n [-COCH ₂ CH(C ₂ H ₅)O-] _n PHV content 8 wt. %	10g	32.40
1.090	250mL	5	34.00		Produced via a controlled fermentation process using microorganisms. Biodegradable polymer		
	100g	5	17.00	40,312-1	Poly(3-hydroxybutyric acid-co-3-hydroxyvaleric acid), natural origin [80181-31-3] [-COCH ₂ CH(CH ₃)O-] _n [-COCH ₂ CH(C ₂ H ₅)O-] _n PHV content 12 wt. %	100g	207.80
	250g	5	34.00		Produced via a controlled fermentation process using microorganisms. Biodegradable polymer		
00 cps	100mL	5	17.70	49,206-6	Poly(2-hydroxyethyl methacrylate) [25249-16-5] [-CH ₂ C(CH ₃)(CO ₂ CH ₂ CH ₂ OH)-] _n d 1.150 FT/IR 1(2),1194C-RAS 1(2),3167F Crystall. Average M _w ca. 300,000	1g	13.20
40 ATOR	250mL	5	32.10			10g	57.00
	100mL	5	17.70	18,213-3	Poly(2-hydroxypropyl methacrylate) [25703-79-1] [-CH ₂ C(CH ₃)(CO ₂ CH ₂ CH(OH)CH ₃)-] _n , FT/IR 1(2),1190C Safety 2,2877A RAS 1(2),3165K Crystall.	25g	113.80
	250mL	5	32.10			10g	68.40
	100mL	5	17.70			25g	134.20
	250mL	5	32.10				
/12 page 1240							
page 1240							
140, d 1.100	250mL	5	20.30				
age 1240							
	100g	5	17.00	44,668-6	Poly(4-hydroxystyrene), see Poly(4-vinylphenol)	1g	18.50
	250g	5	34.00			10g	41.40
72.16kg, DIN				44,669-6	Poly(indene-co-coumarone) [35343-70-5] d 1.140 Fp >230°F(110°C) Ftcs. Average M _w ca. 735. 10 wt. % coumarone	1kg	18.50
t80. Tg 65°, Tm						3kg	41.40
4-6) mp 33°	250g	5	21.30	19,185-7	Poly(isobornyl methacrylate) [84114-51-8] FT/IR 1(2),1194B RAS 1(2),3167E ★ Beads. Average M _w ca. 554,000 (GPC). Tg 110°. Solubility parameter 8.1	10g	42.60
D. Tm (DSC,	1kg	5	58.00	18,145-6	Poly(isobornyl methacrylate) [8003-27-4] [-CH ₂ C(CH ₃) ₂ -] _n , nD 1.5045 d 0.920 FT/IR 1(2),11828 Safety 2,2878B RAS 1(2),3151N, RTECS ID 1010000 Stabil/chunk. Stabilized with 500 ppm 2,6-di-tert-butyl-4-methylphenol. Average M _w ca. 420,000, M _w ca. 500,000, M _w ca. 200,000 (GPC/MALLS). Tg -76°. Tm 1.5°. Solubility parameter 7.7	100g	48.30
ipic acid] diol C)	250mL	5	20.50			250g	60.70
y 2.1	1L	5	58.50				
H_2O , nD 1.4810	25g	5	101.90	18,146-3	Polyisobutylene [8003-27-4] [-CH ₂ C(CH ₃) ₂ -] _n Stabil/chunk. Stabilized with 500 ppm 2,6-di-tert-butyl-4-methylphenol. Average M _w ca. 1,200,000, M _w ca. 1,000,000, M _w ca. 600,000 (GPC/MALLS)	100g	41.40
E LIQUID TOXIC						250g	74.60
sox M. ca.							



44-570-3



44-868-8



...19,195-7

10. **RELATED PROCEEDINGS APPENDIX**

None.